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Attorney Docket No. 980689/HG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Shinichi KURAKATA et al.
Serial No. : 09/212,556
Filed : December 16, 1998
For : METHODS AND COMPOSITIONS
FOR THE TREATMENT AND
PREVENTION OF TUMORS...
Art Unit : 1623
Examiner : Howard Owens, Jr.

DECLARATION UNDER 37 CFR 1.132

Dr. Shinichi KURAKATA, declares that he is a co-inventor of the invention described and claimed in the above-referenced application.

He graduated from the University of Tokyo in 1976 and received a doctorate degree in 1985 (Ph.D., Pharmaceutical Sciences, University of Tokyo).

He has worked for Sankyo Company, Ltd. of Tokyo, Japan (assignee of record) since 1978 and presently holds the position of Vice Director (Biological Research Laboratories). He is also a General Manager in Cancer Research in the Laboratories.

The following testing was done under his supervision and control to compare the activity of Naproxen with the compounds required by the claims in the above-referenced application.

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The comparison testing was conducted using the same procedures as described in Example 1 of the specification of the above-referenced application, except that test compounds were administered every day for the first five days and that the body weight recovery rates were determined based on the weight gain on day 23 instead of day 19, after tumor cell transplantation.

The results of the testing are shown in the following Table:

Administered Compound	Dose (mg/kg)	Weight Gain (g)	Body Weight Recovery Rate (%)
Compound 2-78	1	3.1	115
	0.3	1.6	71
	0.1	-0.5	9
Compound 1-94	1	3.1	115
	0.3	1.5	68
	0.1	-1.1	-9
Naproxen	10	0.4	35
	1	-1.6	-24
	0.1	-0.9	-3
Control Group 1	-	-0.8	0
Control Group 2	-	2.6	100

As is evidenced by the results of the tests, Naproxen showed 35% recovery at a dosage of 10 mg/kg. In comparison, both compounds required in the present claims showed a recovery of better than 100% at the dosage of 1 mg/kg and about 70% recovery at the dosage of 0.3 mg/kg. Thus, based on the comparative test data, the compounds required in the present invention claims have

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much stronger activity against cachexia than does Naproxen. Such activity would not have been expected by persons skilled in the art.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: September 10, 2002

Shinichi Kurakata
Shinichi KURAKATA